JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

WILLIAM F. BARKER, et al.

(b) County of Residence of First Listed Plaintiff Alamance Co., NC
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

Thomas P. Cartmell, Wagstaff & Cartmell LLP, 4740 Grand Ave., Ste. 300, Kansas City, MO 64112 Ph: 816-701-1100

DEFENDANTS

GLAXOSMITHKLINE, LLC, formerly SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE

County of Residence of First Listed Defendant Philadelphia County
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

Nina Gussack, Esq., Pepper Hamilton LLC, 3000 Two Logan Square, Philadelphia, PA 19103 - Ph. 215-981-4000

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☒ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

☐ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☒ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**: Title 26 USC 1332

Brief description of cause: Pharmaceutical product liability

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND $ 75,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☑ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE Honorable Cynthia Rufe DOCKET NUMBER 07-md-1871

DATE 11/12/2010

SIGNATURE OF ATTORNEY OF RECORD Thomas P. Cartmell

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

WILLIAM F. BARKER, SR.,, ET AL. (See addendum attached for additional plaintiffs),	:	CIVIL ACTION
v.	:	
GLAXOSMITHKLINE LLC, FORMERLY SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,	:	NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

November 12, 2010	Thomas P. Cartmell	Plaintiff
Date	**Attorney-at-law**	**Attorney for**
816-701-1100	816-531-2372	tcartmell@wcllp.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

ADDENDUM TO CASE MANAGEMENT TRACK DESIGNATION FORM

Plaintiff Name Address

William F. Barker, Sr., 2422 Hwy 119, Mebane, NC 27302

Linda D. Biggs, 2228 Cid Road, Lexington, NC 27292

Linell Smith Brewington, 128 Breckenridge Drive, Raeford, NC 28376

Donald L. Duncan, 1115 Phelps Road, Hillsborough, NC 27278

Cynthia Graham, 239 Webb Loop Road, Mount Gilead, NC 27603

Olin Haltom, 197 Davis Avenue, Clemmons, NC 27012

Anna Ingram, 146 Philadelphia Drive, Rockingham, NC 28379

Margaret Kennedy, 407 Round Meadows Drive, Kernersville, NC 27284

Regina Lawson, Obo Loretta Stevens Lawson, Dec., 1632 Hwy 704 W, Lawsonville, NC 27022

William Little obo Kathleen Little, Dec., 1459 London Drive, Deep River, NC 27260

Jennie Lowry Obo James Lowry, Dec., 306 Nettle Knob Trail, Lowgap, NC 27024

Linda B. Owen, 455 Eller Road, Rockwell, NC 28138

Rexford N. Proctor, 5643 Riverside Acres Ct., Trinity, NC 27370

Carolyn V. Pulliam, 1143 Jackson Street, Burlington, NC 27217

Baxter Riggsbee, 3784 Mt. Gilead Church Road, Pittsboro, NC 27312

Charles Tilley, 4245 Sherlie Weavil Road, Eller, NC 27107

Thomas Spinks, 5266 Fox Grove Rd., Ramseur, NC 27316

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: William F. Barker, Sr., 2422 Hwy. 119, Mebane, NC 27302 (see attached addtemdum for additional plaintiffs)

Address of Defendant: One Franklin Plaza, Philadelphia, PA 19102

Place of Accident, Incident or Transaction: _____

(*Use Reverse Side For Additional Space*)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes☐ No☐

Does this case involve multidistrict litigation possibilities? Yes☐ No☐

RELATED CASE, IF ANY:

Case Number: 07-md-1871 Judge Cynthia Rufe Date Terminated: _____

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?

Yes☐ No☒

2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?

Yes☒ No☐

3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court?

Yes☐ No☒

4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?

Yes☐ No☒

CIVIL: (Place ✔ in ONE CATEGORY ONLY)

A. *Federal Question Cases*:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases (Please specify)

B. *Diversity Jurisdiction Cases*:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☒ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases (Please specify)

ARBITRATION CERTIFICATION

(*Check Appropriate Category*)

I, Thomas P. Cartmell, counsel of record do hereby certify:

☐ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

DATE: 11/12/10 Thomas P. Cartmell MO # 45366

Attorney-at-Law Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: _____ _____ _____

Attorney-at-Law Attorney I.D.#

CIV. 609 (6/08)

William F. Barker, Sr.

Linda D. Biggs

Linell Smith Brewington.

Donald L. Duncan

Cynthia Graham

Olin Haltom

Anna Ingram

Margaret Kennedy

Regina Lawson, Obo Loretta Stevens Lawson, Dec.

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Rexford N. Proctor

Carolyn V. Pulliam

Baxter Riggsbee

Charles Tilley

Thomas Spinks

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

WILLIAM F. BARKER, SR., LINDA D. BIGGS, LINELL SMITH BREWINGTON, DONALD L. DUNCAN, CYNTHIA GRAHM, OLIN HALTOM, ANNA INGRAM, MARGARET KENNEDY, REGINA LAWSON individually and on behalf of LORETTA STEVENS LAWSON, Deceased, WILLIAM LITTLE individually and on behalf of KATHLEEN LITTLE, Deceased, JENNIE LOWRY individually and on behalf of JAMES LOWRY, Deceased, LINDA B. OWEN, REXFORD N. PROCTOR, CAROLYN V. PULLIAM, BAXTER RIGGSBEE, CHARLES TILLEY, and THOMAS SPINKS	)	
Plaintiffs,	)	CIVIL NO.
v.	)	
GLAXOSMITHKLINE LLC, formerly SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,	)	**COMPLAINT AND JURY DEMAND**
Defendant.	)	

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs, by and through their undersigned attorneys, Wagstaff & Cartmell, LLP, on behalf of themselves individually, hereby sue the defendant, GLAXOSMITHKLINE LLC (GSK LLC), formerly SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, purporting to be a Delaware limited liability corporation which

has its principal place of business at One Franklin Plaza, Philadelphia, Pennsylvania 19101, allege and state the following:

STATEMENT OF THE CASE

1. This is an action brought by Plaintiffs for the personal injuries Plaintiffs suffered following ingestion of Avandia, as the direct and proximate result of the wrongful conduct of the Defendant, GLAXOSMITHKLINE LLC (GSK LLC), formerly SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, (herein referred to as "Defendant" or "GSK"), in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the widely-used diabetes prescription drug Avandia (rosiglitazone).

2. PTO 4 originally permitted filing of multi-party complaints to provide for an efficient and cost-effective prosecution of cases in this MDL. During negotiations regarding the tolling agreement and as consideration for the agreed to Tolling Agreement, plaintiffs agreed with GSK to submission of an Order modifying PTO 4 and removing the right to file multi-party complaints. Plaintiffs' agreement to forego PTO 4's multi-party filing procedures, was made in reliance on the negotiated language of the Tolling Agreement and absent such reliance Plaintiffs would not have agreed to modify PTO 4. This was also memorialized in the Tolling Agreement which provides that its terms cannot be modified absent mutual consent of the parties. Under the agreed to and negotiated Tolling Agreement, GSK agreed to provide tolling to claimants who provided evidence that they had ordered medical records. This was a material term of the Agreement and was the subject of negotiation. Plaintiffs relied upon this term of the Agreement for over one year to toll thousands of cases. On or about November 1, 2010,

GSK unilaterally and without notice or Court approval, refused to provide tolling to any claimant absent not only evidence that records had been ordered (as expressly set forth in the Tolling Agreement) but that the records be provided. That is, absent provision of the records, GSK refused to honor its agreement to provide tolling. This new "requirement" which GSK unilaterally imposed directly conflicts with the terms of the Tolling Agreement which simply requires evidence that records were ordered. As such, GSK has breached and/or anticipatorily breached the Tolling Agreement. GSK's action has effectively acted to prohibit on a mass scale the tolling of cases. As a result of this breach, Plaintiffs are filing multi-party complaints under PTO 4's provisions which were altered only in reliance on GSK's continued compliance with the negotiated Tolling Agreement. In addition, under the Tolling Agreement should GSK "mass terminate" tolling, PTO 4's multi-party filing provision is reinstated. GSK's actions effectively and constructively act as a mass termination of tolling.

PARTIES AND JURISDICTION

3. The Plaintiffs in this action are residents and citizens of various counties in the State of North Carolina, all of which are in the confines of the Middle District of North Carolina. See 28 USC 102(a). The Plaintiffs were diagnosed with diabetes and purchased and used the diabetic drug Avandia.

4. As a result of using Defendant's product, Avandia, and Defendant's negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling, and/or sale of Avandia, Plaintiffs developed severe health problems, including but not limited to, death, myocardial infarction, congestive heart failure, cerebrovascular accident,

atherosclerotic heart disease, and various other cardiovascular, cardiopulmonary, renal and other health problems.

5. As stated above, the Court has provided for the filing of the instant action directly into this Court and, specifically, into MDL No. 1871. Plaintiffs state that but for this allowance, Plaintiffs would have filed in the United States District Court for the Middle District of North Carolina. Therefore, Plaintiffs respectfully request that at the time of transfer of this action back to the trial court for further proceedings this case be transferred to the Middle District of North Carolina.

6. Jurisdiction exists as against Defendant, GLAXOSMITHKLINE LLC (GSK LLC), formerly SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, pursuant to:

a. 28 U.S.C. Section 1332, in that, at all times relevant hereto, Plaintiffs in this action are domiciliaries and citizens of the State of North Carolina, with their true, fixed and permanent homes and residences within the confines of the Middle District of North Carolina; and the Defendant, GLAXOSMITHKLINE LLC (GSK LLC), formerly SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, has its principal business and address at One Franklin Plaza, Philadelphia, Pennsylvania; and Defendant regularly conducts business in the State of Pennsylvania; and the amount in controversy exceeds the sum of $75,000.00 exclusive of interests and costs.

b. 28 U.S.C Section 1391, in that jurisdiction is founded only on diversity of citizenship, and the Eastern District of Pennsylvania is the Judicial District

in which a substantial part of the events or omissions giving rise to the claim occurred.

7. At all times hereinafter mentioned, upon information and belief, Defendant GLAXOSMITHKLINE LLC (GSK LLC) purports to be a limited liability corporation organized and existing under the laws of the State of Delaware but which maintains its principal place of business in the State of Pennsylvania.

8. At all times hereinafter mentioned, upon information and belief, Defendant GLAXOSMITHKLINE LLC (GSK LLC) is a foreign limited liability corporation authorized to do business in the State of North Carolina.

9. At all times hereinafter mentioned, upon information and belief, Defendant GLAXOSMITHKLINE LLC (GSK LLC) is a business entity actually doing business in the State of North Carolina.

10. At all times hereinafter mentioned, upon information and belief, Defendant SMITHKLINE BEECHAM CORPORATION was and still is a corporation organized and existing under the laws of the State of Pennsylvania.

11. At all times hereinafter mentioned, upon information and belief, Defendant SMITHKLINE BEECHAM CORPORATION was and still is a foreign corporation authorized to do business in the State of North Carolina.

12. At all times hereinafter mentioned, upon information and belief, Defendant SMITHKLINE BEECHAM CORPORATION was and still is a business entity actually doing business in the State of North Carolina.

13. At all times hereinafter mentioned, upon information and belief, Defendant GLAXOSMITHKLINE was and still is a corporation organized and existing under the laws of the State of Pennsylvania.

14. At all times hereinafter mentioned, upon information and belief, Defendant GLAXOSMITHKLINE was and still is a foreign corporation authorized to do business in the State of North Carolina.

15. At all times hereinafter mentioned, upon information and belief, Defendant GLAXOSMITHKLINE was and still is a business entity actually doing business in the State of North Carolina.

16. At all times hereinafter mentioned, upon information and belief, Defendant SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE was and still is a corporation organized and existing under the laws of the State of Pennsylvania and with its principal place of business in the State of Pennsylvania.

17. At all times hereinafter mentioned, upon information and belief, Defendant SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE was and still is a foreign corporation authorized to do business in the State of North Carolina.

18. At all times hereinafter mentioned, upon information and belief, Defendant SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE was and still is business entity actually doing business in the State of North Carolina.

19. At all times hereinafter mentioned, upon information and belief, Defendant presently markets and sells the drug Avandia.

20. At all times hereinafter mentioned, upon information and belief, Defendant engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Avandia, and in pursuance of this business, transacts business within the State of Pennsylvania and contracts to provide goods and services in the State of Pennsylvania.

21. At all times hereinafter mentioned, upon information and belief, Defendant committed a tortious act, which caused the injury to Plaintiffs, citizens of the State of North Carolina.

22. At all times hereinafter mentioned, upon information and belief, Defendant committed a tortious act outside the State of Pennsylvania, which caused injury to Plaintiffs, citizens of the State of North Carolina.

23. At all times hereinafter mentioned, upon information and belief, Defendant regularly does and solicits business and engages in a persistent course of conduct in the State of North Carolina, deriving substantial revenue from goods and products consumed in the State of North Carolina.

24. At all times hereinafter mentioned, upon information and belief, Defendant expects or should reasonably expect its acts to have consequences in the State of North Carolina, and derives substantial revenue from interstate or international commerce.

BACKGROUND STATEMENT OF THE CASE

25. Type 2 diabetes is the most common form of diabetes, afflicting 18 million Americans and 200 million people worldwide. This form of diabetes occurs when the body does not make enough insulin (a hormone needed to convert sugar and

other food into energy) or cannot effectively use what it manages to produce. Further, diabetics are prone to heart problems, and indeed, two-thirds of diabetics die of heart problems.

26. Avandia, created and marketed by GSK, is designed to treat persons with Type 2 diabetes by helping sensitize cells to insulin, thereby greatly assisting in blood-sugar control. It also is combined with metformin and sold as Avandamet and combined with a sulfonylurea (glimepiride) and sold as Avandaryl. Only one other drug like it, pioglitazone, sold as Actos and Actoplus Met by Takeda Pharmaceuticals, is sold in the United States. In 2006, Avandia represented 37% of the U.S. market for oral diabetes treatments. Thus, the U.S. market for such drugs is huge, and Avandia faces only one competitor for that market.

27. Avandia had a total U.S. sales of $2.2 billion in 2006, slightly less than the $2.6 billion in total U.S. sales for Actos, according to IMS Health, a healthcare information company. Approximately 13 million Avandia prescriptions were filled in the U.S. last year, with a one-month supply of Avandia selling for between $90 and $170. Avandia is critical to GSK, being the company's second largest selling drug after Advair (an asthma medication).

A. DEFENDANT KNEW OR SHOULD HAVE KNOWN THAT INGESTING AVANDIA INCREASES THE RISK OF MYOCARDIAL INFARCTION, STROKE AND OTHER SERIOUS HEART INJURIES AND DEATH

28. GSK's product Avandia can cause heart injury, excessive fluid retention, fluid-overload disease, congestive heart failure, heart attack, liver damage, liver failure and severe injury to the heart leading to cardiac arrest and death.

29. GSK knew or should have known about these adverse side effects as early as 1999, but failed to adequately warn the consumer public, physicians and the Food and Drug Administration (FDA) of these life threatening cardiovascular risks.

30. In 1999, Dr. John B. Buse, a diabetes expert and head of endocrinology at the University of North Carolina, Chapel Hill, was involved as an investigator in a rosiglitazone study. Following his investigational efforts, he gave a number of speeches at scientific meetings where he opined that rosiglitazone may carry cardiovascular risks.

31. GSK attempted to silence Dr. Buse by threatening him with a $4 million lawsuit, characterizing him a liar and telling Dr. Buse's department chair that he was "for sale."[1],[2] In response to GSK's pressure, Dr. Buse sent a three-page letter to the then Chairman of Research and Development, Dr. Tadataka Yamada. Dr. Buse wrote, "I may disagree with GSK's interpretation of that data … I am not for sale … Please call off the dogs. I cannot remain civilized much longer under this kind of heat." Eventually, after the intimidation, Dr. Buse signed a statement that GSK used to help ease investor concerns.

32. Nevertheless, on March 15, 2000, John Buse, M.D. wrote a letter to the FDA again raising concerns about a "worrisome trend in cardiovascular deaths and severe adverse events" associated with Avandia:

> I would like you to know exactly what my concerns are regarding Rosiglitazone as a clinical scientist and my approach as a clinician. On the basis of the increase in LDL concentration seen in the clinical trial program (whether the number we accept as the truth is the 18.6% at 4 mg bid in the package insert or the "average of 12%" now being discussed)

[1] John Buse, M.D. Congressional Hearing Transcript (June 6, 2007).

[2] Committee Staff Report, United States Senate, Committee on Finance, *Intimidation of Dr. John Buse and Diabetes Drug Avandia* (Nov. 2007).

> one would expect an increase in cardiovascular events....Based on studies with statins and plasmapheresis, changes in LDL concentration can be associated with substantial changes in vascular reactivity and endothelial function over a time course of days to weeks.
>
> In short, the lipid changes with troglitazone and pioglitazone can only be viewed as positive. They are very similar in nature....As mentioned above, I remain concerned about the lipid changes with rosiglitazone....Rosiglitazone is clearly a very different actor. I do not believe that rosiglitazone will be proven safer than troglitazone in clinical use under current labeling of the two products. In fact, rosiglitazone may be associated with less beneficial cardiac effects or even adverse cardiac outcomes.[3]

33. After hearing allegations that Dr. Buse was intimidated, the United States Senate Committee on Finance, began an investigation and "intensive review" of documents and found that "it is apparent that the original allegations, regarding Dr. Buse and GSK's attempts at silencing him are true; according to relevant emails, GSK executives labeled Dr. Buse a "renegade" and silenced his concerns about Avandia by complaining to his superiors and threatening a lawsuit."

34. The Senate Committee stated in its report that "[t]he documents in the Committee's possession raise serious concerns about the culture of leadership at GSK. Even more serious perhaps is our fear that the situation with Dr. Buse is part of a more troubling pattern of behavior by pharmaceutical executives."

35. The Senate Committee noted that "[t]he effect of silencing this criticism is, in our opinion, *extremely serious*. At a July 30, 2007, safety panel on Avandia, FDA scientists presented an analysis estimating that Avandia caused approximately 83,000 excess heart attacks since coming on the market. Had GSK considered Avandia's increased cardiovascular risk more seriously when the issue was first raised in 1999 by

[3] Letter from Dr. Buse to FDA (March 15, 2000).

Dr. Buse, instead of trying to smother an independent medical opinion, some of these heart attacks may have been avoided." (internal footnote omitted).

36. Furthermore, in 2005, GSK performed an overview analysis of multiple Avandia trials, referred to as a "meta-analysis", and shared the preliminary results with the Food and Drug Administration ("FDA") in September 2005. Almost one year later, in August 2006, a more complete version of the meta-analysis was provided to the FDA. The results of GSK's analysis showed that patients taking Avandia had a 31% higher risk of adverse cardiovascular events such as heart attack due to obstruction of blood flow.

37. Not only was GSK aware of the dangers posed by Avandia, but data from these studies continued to be made available to GSK. On May 21, 2007, Dr. Steven E. Nissen, a prominent cardiologist associated with the Cleveland Clinic, published a study in the *New England Journal of Medicine* of his analysis of 42 studies comprising of approximately 28,000 people who took Avandia. These were on-line databases of GSK studies that were available on the Internet. Dr. Nissen's meta-analysis revealed a 43% higher risk of heart attack for those taking Avandia compared to people taking other diabetes drugs or no diabetes medication, and people taking Avandia suffered such adverse events at a rate of 1.99%, as opposed to 1.51% for other patients. Further, Dr. Nissen's analysis showed a 64% elevated risk of death from cardiovascular causes.

38. On May 21, 2007, the FDA issued a Safety Alert on Avandia showing that there is a potentially significant risk of heart attack and heart-related deaths in patients taking Avandia.

39. It was not until November 19, 2007, when GSK was required by the FDA, that GSK updated the Avandia label with a Black Box warning regarding myocardial

ischemia, stating: "...A meta-analysis of 42 clinical studies (mean duration 6 months; 14,237 total patients), most of which compared AVANDIA to placebo, showed AVANDIA to be associated with an increased risk of myocardial ischemic events such as angina or myocardial infarction. Three other studies (mean duration 41 months; 14,067 patients), comparing AVANDIA to some other approved oral antidiabetic agents or placebo, have not confirmed or excluded this risk. In their entirety, the available data on the risk of myocardial ischemia are inconclusive.

B. DEFENDANT KNEW OR SHOULD HAVE KNOWN THAT INGESTING AVANDIA INCREASES THE RISK OF CONGESTIVE HEART FAILURE

40. By at least 2002, there were serious and substantial reports of Avandia-related heart failure that resulted in hospitalizations. At the time, FDA scientists recommended the drug's label be revised to reflect the possible risk of heart failure as revealed by post-marketing reports. In 2002, the FDA recommended the Defendant mention post-marketing cases of heart failure.[4]

41. Despite this 2002 recommendation to mention post-marketing cases of heart failure the labeling at the time Plaintiffs began ingesting Avandia was wholly inadequate to apprise Plaintiffs of the true risks associated with Defendant's Avandia.

42. A clinical trial sponsored by the Defendant revealed that Avandia users were more than twice as likely to develop congestive heart failure than patients using other diabetes drugs.

43. Researchers at Wake Forest University conducted an analysis of four long-term studies involving more than 14,000 patients and the study also concluded that

[4] Internal Food and Drug Administration Memo (2002).

Avandia doubles the risk of heart failure and increases the risk of heart attack by more than 40%.

44. Dr. Sonal Singh, co-author of the Wake Forest University study has stated that risk of developing heart failure due to Avandia is 1 in 30 and the risk of having a heart attack is 1 in 220.

45. Avandia has been the subject of controversy since May when the *New England Journal of Medicine* published a meta-analysis of 44 studies that linked the drug to an increased risk of heart attacks.

46. Following the May 21, 2007 NEJM publication of the Nissen/Wolski meta-analysis, the FDA issued a safety alert for Avandia and advised patients who take it to consult their doctors.

47. At a congressional hearing held on June 6, 2007, the FDA indicated that a black box warning should be added to rosiglitazone (Avandia), for increased risk of heart failure.

48. It was not until August 14, 2007, when GSK was required by the FDA, that GSK updated the Avandia label with a Black Box warning regarding congestive heart failure stating: "Thiazolidinediones, including rosiglitazone, cause or exacerbate congestive heart failure in some patients (see WARNINGS). After initiation of AVANDIA, and after dose increases, observe patients carefully for signs and symptoms of heart failure (including excessive, rapid weight gain, dyspnea, and/or edema). If these signs and symptoms develop, the heart failure should be managed according to current standards of care. Furthermore, discontinuation or dose reduction of AVANDIA must be considered. AVANDIA is not recommended in patients with symptomatic heart failure.

Initiation of AVANDIA in patients with established NYHA Class III or IV heart failure is contraindicated."

C. GSK CONCEALED THE RISKS OF AVANDIA FROM THE PUBLIC, MEDICAL COMMUNITY AND THE FOOD & DRUG ADMINISTRATION IN VIOLATION OF THE FEDERAL REGULATIONS

49. To date, GSK has failed to adequately warn or inform consumers, such as Plaintiffs' prescribing physicians, of the known defects in Avandia that can lead to increased risk of cardiovascular events, specifically including congestive heart failure and myocardial infarction, fraudulently concealed these defects and made misrepresentations to the damage and detriment of Plaintiffs.

50. In fact, on July 17, 2001, the United States Food and Drug Administration (FDA) issued a Warning letter to Defendant arising from oral misrepresentations made by Defendant at the 10th Annual American Association of Clinical Endocrinologists (AACE) Meeting in San Antonio, Texas, on May 2-6, 2001, which denied the existence of serious new risks associated with Avandia at GSK's promotional exhibit booth. Additionally, GSK displayed exhibit panels (AV013G) at this meeting that minimized new risks associated with Avandia.

51. The FDA found that Defendant "promotional activities that minimize serious new risks are particularly troublesome because we have previously objected, in two untitled letters, to your dissemination of promotional materials for Avandia that failed to present any risk information about Avandia or minimized the hepatic risk associated with Avandia. Despite your assurances that such violative promotion of Avandia had ceased, your violative promotion of Avandia has continued."

52. On March 25, 2008, the FDA sent yet another Warning Letter to GSK wherein the FDA outlined its findings following an inspection at GSK's corporate headquarters located in North Carolina. The inspection focused on GSK's "compliance with Postmarketing Adverse Drug Experience (PADE) reporting requirements and other postmarketing reporting requirements related to Avandia (rosiglitazone maleate) approved by the FDA on May 25, 1999, under NDA 21-071." The FDA inspection revealed that GSK:

> failed to report data relating to clinical experience, along with other data and information, for Avandia, as required under Section 505(k)(1) of the Federal Food, Drug, and Cosmetic Action (the Act) [21 U.S.C. § 355(k)(1)] and Title 21 of the Code of Federal Regulations (21 CFR) Sections 314.80 and 314.81. In particular, the inspection found that your firm failed to report multiple postmarking studies involving Avandia in mandatory Periodic and/or NDA Annual Reports. Failure to comply with Section 505(k) of the Act is a prohibited act under Section 301(e) of the Act [21 U.S.C. § 331(e)].[5]

53. The FDA stated in its Warning Letter that "the specific violations noted in this letter are *serious* and may be *symptomatic* of underlying postmarketing safety reporting failures." (emphasis added). The letter was not an inclusive list of all violations and the FDA reminded GSK that "[i]t is your responsibility to ensure adherence to each requirement of the Act and its regulations." (emphasis added).

54. Moreover, the FDA also makes it illegal to receive, introduce, or deliver for introduction into interstate commerce any drug that is "misbranded." 21 U.S.C. § 331(a)-(c).

1) A drug is misbranded if any one of several circumstances exists, such as:

   a. *False or Misleading*. A drug is misbranded if its labeling is "false or misleading in any particular." 21 U.S.C. § 352(a).

[5] FDA Warning Letter to GlaxoSmithKline (March 25, 2008).

b. *Prominence*. A drug is misbranded if required information is not prominently placed with such conspicuousness and in such terms as to make it likely to be read and understood by an ordinary individual. 21 U.S.C. § 352(c).

c. *Truth in Advertising*. A prescription drug is misbranded if its advertising does not provide a "true statement" with respect to side effects, contraindications, or effectiveness. 21 U.S.C. § 352(n). Advertising cannot be "false, lacking in fair balance, or otherwise misleading." 21 C.F.R. § 202.1(e).

2) It will be so deemed if, for example, it:

a. Contains a representation or suggestion, not approved for use in the labeling, that the drug is better, safer, more effective, or effective in a broader range of conditions than demonstrated by substantial evidence. 21 C.F.R. § 202.1(e)(6)(i);

b. Contains an unsupported comparative claim or superiority claim. 21 C.F.R. § 202.1(e)(6)(i) and (ii);

c. Contains unsupported favorable information or opinions; 21 C.F.R. § 202.1(e)(6)(iii);

d. Selectively presents favorable information on safety or side effects. 4521 C.F.R. § 202.1(e)(6)(iv);

e. Suggests that study information has more general application. 4621 C.F.R. § 202.1(e)(6)(v);

f. Uses literature references that do not support the claim in question. 4721 C.F.R. § 202.1(e)(6)(vi);

g. Uses data that have no clinical significance. 4821 C.F.R. § 202.1(e)(6)(vii);

h. Uses statements from authorities out of context, or ignoring negative or inconsistent views. 4921 C.F.R. § 202.1(e)(6)(viii)-(ix);

i. Uses literature, quotations, or references to recommend or suggest an unapproved indication or to inaccurately support an approved indication. 21 C.F.R. § 202.1(e)(6)(x)-(xi); or

j. Cites scientific studies that are defective in construction or contain criteria making them inapplicable to the sponsor's purpose. 5121 C.F.R. § 202.1(e)(6)(xiii)-(xx).

55. Based on these events and other information relating to Defendant's acts and omissions relating to Avandia as alleged herein, the following violations have been committed by Defendant:

a. Failure to promptly review and submit to the FDA adverse drug experience (ADE) reports as required by 21 CFR 314.80.

b. Failure to submit documented review and maintenance of the adverse drug event records related to these applications as required by 21 CFR 314.80 (i).

c. Failure to develop adequate written procedures for the surveillance, receipt, evaluation, and reporting of post-marketing adverse drug experience to FDA, as required by 21 CFR 314.80 (b).

d. Failure to submit all prescription drug advertising and promotional labeling (including mailing pieces and labeling designed to contain samples) to FDA at the time such materials are initially disseminated or published. 21 C.F.R. § 314.81(b)(3)(i).

e. Misbranding a drug through false or misleading information. 21 U.S.C. § 352(a).

f. Misbranding a drug where its advertising does not provide a "true statement" with respect to side effects, contraindications, or effectiveness. 21 U.S.C. § 352(n).

56. As alleged herein, as a direct and proximate result of the Defendant's negligence and wrongful conduct, including violations of the federal regulations, and the unreasonably dangerous and defective characteristics of the subject product, the Plaintiffs suffered severe and permanent physical injuries which are continuing in nature.

D. GSK CONTINUES TO MISREPRESENT THE SAFETY AND EFFICACY OF AVANDIA

57. Despite GSK's longstanding knowledge of these dangers, Avandia's label only warns about possible heart failure and other heart problems when taken with insulin. GSK failed to warn and disclose to consumers that Avandia significantly increased the risk of adverse cardiovascular events. Furthermore, the proper and effective use of Avandia by Plaintiffs was impaired due to GSK's failure to warn of Avandia's defects and GSK's failure to properly and adequately set forth such warnings in Avandia's drug labeling.

58. GSK knew of these dangerous defects in Avandia from the many trials which it performed and to which it had access and from its own analysis of these studies, but took no action to adequately warn or remedy the defects, but instead concealed, suppressed and failed to disclose the dangers. Even in the face of Dr. Nissen's study, GSK continues to fail to warn of these dangers through revised drug labeling.

59. Not only has GSK failed to disclose in its labeling or advertising that Avandia is actually dangerous for diabetics, GSK has represented and continues to

represent that they manufacture and/or sell safe and dependable pharmaceuticals with safety as its first concern:

> Like all innovative pharmaceutical companies, we carry out a series of clinical trials to test each investigational drug for the potential to become a new medicine.
>
> ***
>
> Phase I trials typically involve health volunteers. *These trials study the safety of the drug and its interaction with the body,* for example, its concentration and duration in the blood following various doses, and begin to answer such questions as whether the drug inhibits or amplifies the effects of other medicines that might be taken at the same time.
>
> Phase II studies enroll patients with the illness an investigational drug is designed to treat. These trials evaluate whether the drug shows favourable effects in treating an illness and seek to determine the proper dose. They provide an opportunity to explore the therapeutic potential of the drug in what may be quite different illnesses. *The evaluation of safety continues.*
>
> If Phase II results have been encouraging, Phase III trials, the largest part of a clinical-development program, go forward. *Phase III trials are designed to provide the substantial evidence of efficacy and safety required,* in addition to data from earlier-phase trials, before regulatory agencies will approve the investigational drug as a medicine and allow it to be marketed.

http://www.gsk.com/research/clinical/index/html (emphasis supplied).

60. GSK has also strongly touted its commitment to improving the quality of life: "We have a challenging and inspiring mission: to improve the quality of human life by enabling people to do more, feel better and live longer." http://www.gsk.com/about/index.htm.

61. Based on these representations, upon which Plaintiffs relied, including the omission from the Avandia labeling of the danger of increased risk of adverse

cardiovascular events as a result of ingesting Avandia, Plaintiffs purchased and ingested Avandia believing that the drug would be safe and effective.

62. In fact, however, Avandia poses significant safety risks due to defects in its chemical design and inadequate labeling.

63. As a result of GSK's omissions and/or misrepresentations, Plaintiffs ingested Avandia and suffered injury.

COUNT I
EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS:

64. Plaintiffs repeat and reiterate paragraphs 1-63 as if fully set forth herein.

65. The running of any statute of limitations has been tolled by reason of Defendant's fraudulent concealment. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiffs and Plaintiffs' prescribing physicians the true risks associated with taking Avandia.

66. As a result of Defendant's actions, Plaintiffs and, upon information and belief, Plaintiffs' prescribing physicians were unaware, and could not reasonably know or have learned through reasonable diligence that he had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendant's acts and omissions.

67. Furthermore, Defendant is estopped from relying on any statue of limitations because of its fraudulent concealment of the true character, quality and nature of Avandia. Defendant was under a duty to disclose the true character, quality and nature of Avandia because this was non-public information over which the Defendant had and continues to have exclusive control, and because the Defendant knew that this

information was not available to the Plaintiffs, medical providers and/or to their facilities. In addition, the Defendant is estopped from relying on any statue of limitations because of its international concealment of these facts.

68. The Plaintiffs had no knowledge that the Defendant was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the Defendant, the Plaintiffs could not have reasonably discovered the wrongdoing at any time prior. Also, the economics of this fraud should be considered. The Defendant had the ability to and did spend enormous amounts of money in furtherance of its purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiffs and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on only the Defendant's representations.

COUNT II
DESIGN DEFECT

69. Plaintiffs repeat and reiterate paragraphs 1-68 as if fully set forth herein.

70. At all times material to this action, GSK was responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Avandia.

71. The subject product is defective and unreasonably dangerous to consumers.

72. Avandia is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

73. At all times hereinafter mentioned, the drug Avandia was not suited for the treatment of diabetes, and was not safe and effective for the treatment of diabetes, even though GSK directly and indirectly advertised, marketed and promoted Avandia for such use.

74. At all times hereinafter mentioned, the drug Avandia was not safe and was not suited for the purposes for which GSK, directly and indirectly, advertised, marketed and promoted the drug at the time GSK designed, manufactured, distributed and sold the drug and placed the drug in the stream of commerce.

75. Avandia was defective and unreasonably dangerous when it left control of GSK in one or more of the following manners:

a) The risk associated with use of Avandia far outweighed the utility derived from using the medication;

b) Defendant's failed to provide adequate warnings regarding the hazards associated with the use of Avandia;

c) Defendant's product was defectively designed and unreasonably dangerous in design and composition in that other medications could achieve similar results without the risks presented by Avandia; and

d) Avandia failed to comply with express warrantees that the product was safe and effective for human consumption.

76. In addition, at the time the subject product left the control of GSK, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of the Plaintiffs' injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible, and would have prevented or significantly

reduced the risk of the Plaintiffs' injuries without substantially impairing the product's utility.

77. As a direct and proximate result of the subject product's defective design, the Plaintiffs suffered severe and permanent physical injuries which are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT III
MANUFACTURING DEFECT

78. Plaintiffs repeat and reiterate paragraphs 1-77 as if fully set forth herein.

79. At all time material to this action, GSK was engaged in the business of designing, developing, manufacturing, rebranding, labeling, marketing, distributing and/or selling Avandia.

80. At all times material to this action, Avandia was expected to reach and did reach, consumers in the State of North Carolina and throughout the State of North Carolina, including the Plaintiffs herein without substantial change in the condition in which it was sold.

81. GSK sold and/or distributed Avandia in a condition that posed unreasonable risks from reasonably anticipated use. Avandia was expected to and did reach Plaintiffs without substantial change in condition from the time that it left the control of the Defendant.

82. The defective conditions alleged herein rendered Avandia unreasonably dangerous to the Plaintiffs and proximately caused the injuries and damages for which this lawsuit seeks recovery.

83. At all times material to this action, Avandia was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by GSK in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but not limited to, on or more of the following particulars:

a. When placed in the stream of commerce, Avandia contained manufacturing defects which rendered the product unreasonably dangerous;

b. The subject product's manufacturing defects occurred while the product was in the possession and control of GSK;

c. The subject product was not made in accordance with GSK's specifications or performance standards; and

d. The subject product's manufacturing defects exited before it left the control of GSK.

84. As a direct and proximate result of the subject product's manufacturing defects, the Plaintiffs suffered severe and permanent physical injuries which are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IV
FAILURE TO WARN

85. Plaintiffs repeat and reiterates paragraphs 1-84 as if set forth herein.

86. GSK knew, or in the light of reasonably available knowledge, should have known, of the danger in Avandia that caused the damage for which recovery is sought. The ordinary user or consumer of Avandia would not have realized such dangers.

87. GSK neglected to provide Plaintiffs with warnings that reasonably could have been expected to catch the attention of a reasonably prudent person under similar circumstances taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product. Further, GSK failed to provide warnings which could accurately advise an ordinary consumer of the scope, severity and likelihood of serious injury resulting from use of its product. Had such warnings been provided, the injuries and damages sustained by Plaintiffs could have been avoided.

88. GSK neglected to provide Plaintiffs' prescribing physicians with adequate warnings to accurately advise such physician of the increased severity and likelihood of serious injury resulting from the prescribing and ingestion of Avandia to patients such as Plaintiffs.

89. GSK's product failed to function as expected and there existed feasible design alternatives equally effective and useful that would have had a reasonable probability of preventing the harms sustained by Plaintiffs.

90. At all times hereinafter mentioned, upon information and belief, GSK assumed a strict products liability to persons using Avandia, including Plaintiffs, who sustained injuries, harm and damages by reason of the use of Avandia for purposes directly and indirectly advertised, marketed, and promoted by GSK, including for the treatment of diabetes.

91. As a direct and proximate result of the subject product's defective and inappropriate warnings, the Plaintiffs suffered severe and permanent physical injuries which are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT V
BREACH OF IMPLIED WARRANTY

92. Plaintiffs repeat and reiterate paragraphs 1-91 as if fully set forth herein.

93. GSK designed, manufactured, marketed, distributed, supplied and sold the subject product for the treatment of diabetes.

94. At this time that the GSK manufactured, marketed, distributed, supplied and sold Avandia, they knew of the use for which the subject product was intended and impliedly warranted it to be merchantable quality and safe and fit for such use.

95. The Plaintiffs, individually and through Plaintiffs' prescribing physicians, reasonably relied upon the skill, superior knowledge and judgment of GSK.

96. The Plaintiffs were prescribed, purchased and used the subject product for its intended purpose.

97. Due to the GSK's wrongful conduct as alleged herein, the Plaintiffs could not have known about the nature of the risks and side effects associated with the subject product until after he used it.

98. Contrary to the implied warranty for the subject product, Avandia was not of merchantable quality, and was not safe or fit for its intended uses and purposes, as alleged herein.

99. As a direct and proximate result of GSK's breach of implied warranty, the Plaintiffs suffered severe and permanent physical injuries which are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI
BREACH OF EXPRESS WARRANTY

100. Plaintiffs repeat and reiterate paragraphs 1-99 as if fully set forth herein.

101. At all times hereinafter mentioned, upon information and belief, GSK, by direct and indirect advertising, marketing and promoting Avandia for the treatment of diabetes, and by placing this drug in the stream of commerce knowing that Avandia would be prescribed for the treatment of diabetes, in reliance upon the representations of GSK expressly warranted to all foreseeable users of this drug, including the Plaintiffs, that Avandia was safe and effective for the treatment of diabetes.

102. GSK impliedly warranted in manufacturing, distributing, selling, advertising, marketing and promoting Avandia to all foreseeable users, including Plaintiffs, that Avandia was safe and effective for the purposes for which it had been placed in the stream of commerce by GSK, including for the treatment of diabetes, and that Avandia was reasonably safe, proper, merchantable and fit for the intended purposes, including for the treatment of diabetes.

103. At all times hereinafter mentioned, Plaintiffs relied upon the aforesaid express and implied warranties by GSK.

104. At all times hereinafter mentioned, Plaintiffs' use of Avandia prior to and up to the time of the above-described incident was consistent with the purposes for which

GSK directly and indirectly advertised, marketed and promoted Avandia, and Plaintiffs' use of Avandia was reasonably contemplated, intended and foreseen by GSK at the time of the distribution and sale of Avandia by GSK, and, therefore, Plaintiffs' use of Avandia was within the scope of the above-described express and implied warranties.

105. GSK breached the aforesaid express and implied warranties because Avandia was not safe and effective for the treatment of diabetes, and because Plaintiffs' use of Avandia for the treatment of diabetes, caused or contributed to the incident described herein.

106. As a direct and proximate result of GSK's breach of express warranty, the Plaintiffs suffered severe and permanent physical injuries which are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VII
NEGLIGENCE

107. Plaintiffs repeat and reiterate paragraphs 1-106 as if fully set forth herein.

108. That at all times hereinafter mentioned, GSK was under a duty to exercise reasonable care in the design manufacture, testing, processing, marketing, advertising, labeling, packaging distribution, and sale of Avandia, and GSK knew or should have known that Avandia was not safe and that the user could sustain injuries and harm from the drug.

109. GSK negligently, recklessly, grossly negligently, wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others in that they failed to exercise reasonable care and failed to fulfill the above-stated duty by the manner

that GSK, directly and indirectly, advertised, marketed and promoted Avandia for the treatment of diabetes, even though Avandia, in fact, is not reasonably safe for such use, and furthermore, GSK failed to adequately warn of the increased risk of serious cardio-vascular events which GSK knew or should have known about.

110. GSK further negligently, recklessly, grossly negligently, wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others by manufacturing, distributing, selling, advertising, marketing and promoting Avandia even though such drug was not safe or effective for any purpose because it caused serious cardiovascular events and by failing to adequately warn the public of such risks.

111. The aforesaid incident and the injuries sustained by the Plaintiffs were caused by or were contributed to by the negligence, recklessness, gross negligence, wantonness, willfulness, and conscious and callous disregard of the safety of the public, including the Plaintiffs, on the part of GSK in the design, manufacture, distribution, advertising, marketing and promoting of Avandia as being safe and effective in the treatment of diabetes, and by inducing the public, including the Plaintiffs, and Plaintiffs' prescribing physicians, to believe that Avandia was effective in the treatment of the causes and symptoms of diabetes.

112. GSK failed to exercise reasonable care in the design, manufacture, testing, processing, marketing, advertising, labeling, packaging, rebranding, distribution and/or sale of Avandia in one or more of the following respects:

a) Designing, marketing, processing, advertising, packaging, distributing and/or selling a product that defendant knew, or should have known, carried the risk of serious; life-threatening side effects;

b) Failure to adequately test the product prior to placing the drug Avandia on the market;

c) Failure to use care in designing, developing and manufacturing its product so as to avoid posing unnecessary health risks to users of such product;

d) Failure to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety of Avandia;

e) Failure to advise consumers, such as Plaintiffs, that consumption of Avandia could result in severe and disabling side effects, including but not limited to heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure and severe injury to the heart leading to cardiac arrest and death;

f) Failure to advise the medical and scientific communities of the potential for severe and disabling side effects, including but not limited to heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest, and death;

g) Failure to provide timely and/or adequate warnings about the potential health risks associated with the use of Avandia; and

h) Any and all other acts of negligence with respect to Avandia which may be shown at trial.

113. At all times hereinafter mentioned, upon information and belief, the above-described culpable conduct by GSK was a proximate cause of injuries suffered by the Plaintiffs.

114. At all times hereinafter mentioned, the Plaintiffs did not contribute to Plaintiffs' injuries by reason of any negligence or culpable conduct on the Plaintiffs' part.

115. That as a result of the aforesaid occurrence, the injuries sustained by the Plaintiffs resulting therefrom, the Plaintiffs suffered extensive monetary and pecuniary losses and other compensatory damages were also incurred and paid out including

necessary medical, hospital, and concomitant expenses. In addition, the Plaintiffs were deprived of a chance for safe and effective and/or successful treatment.

116. As a direct and proximate result of GSK's carelessness and negligence, the Plaintiffs suffered severe and permanent physical injuries which are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VIII
PUNITIVE DAMAGES

117. Plaintiffs repeat and reiterate paragraphs 1-116 as if fully set forth herein.

118. At all times material hereto, GSK knew or should have known that the subject product was inherently more dangerous associated with the medication, including the potential for the medication to cause heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest, and death.

119. At all times material hereto, GSK attempted to misrepresent and did misrepresent facts concerning the safety of the subject product.

120. GSK's misrepresentations include knowingly withholding material information from the medical community, the public, including the Plaintiffs herein, and the FDA concerning the safety of the subject product.

121. GSK knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and

safety of the public, including the Plaintiffs herein, in conscious and/or negligent disregard of the foreseeable harm caused by Avandia.

122. GSK intentionally concealed and/or recklessly failed to disclose to the medical community, the public, including the Plaintiffs herein, and the FDA the potentially life threatening side effects of Avandia in order to ensure continued and increased sales.

123. GSK's intentional and/or reckless failure to disclose information deprived the Plaintiffs of necessary information to enable the Plaintiffs to weigh the true risks of using the subject product against its benefits.

124. As a direct and proximate result of GSK's conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiffs, the Plaintiffs suffered severe and permanent physical injuries, including but not limited to death, myocardial infarction, congestive heart failure, cerebrovascular accident, atherosclerotic heart disease, and various other cardiovascular, cardiopulmonary, renal and other health problems. The Plaintiffs endured substantial conscious pain and suffering, both physical and emotional in nature. The Plaintiffs incurred significant expenses for medical care and treatment, suffered lost wages and earning, and was otherwise physically, emotionally and economically injured. The Plaintiffs have suffered severe pecuniary loss. The Plaintiffs seek actual and punitive damages from the GSK as alleged herein.

125. The aforesaid conduct of GSK was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including the Plaintiffs herein, thereby entitling the Plaintiffs to punitive damages in an amount appropriate to punish the GSK and deter them from similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IX
FRAUD

126. Plaintiffs repeat and reiterate paragraphs 1-125 as if fully set forth herein.

127. GSK widely advertised and promoted Avandia as a safe and effective medication.

128. GSK had a duty to disclose material information about serious side effects to consumers such as the Plaintiffs. Additionally by virtue of GSK's partial disclosures about the medication, in which GSK touted Avandia as safe and effective treatment, GSK had a duty to disclose all facts about the risks of use associated with the medication, including the potential for the medication to cause heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest, and death. GSK intentionally failed to disclose this information for the purpose of inducing consumers, such as the Plaintiffs, to purchase GSK's dangerous product.

129. Had the Plaintiffs been aware of the hazards associated with Avandia, the Plaintiffs would not have purchased and/or consumed the product that lead proximately to the Plaintiffs' injuries as alleged herein.

130. GSK's advertisements regarding Avandia made material misrepresentations to the effect that Avandia was a safe and effective treatment, which misrepresentations GSK knew to be false, for the purpose of fraudulently inducing consumers, such as the Plaintiffs, to purchase such product. The Plaintiffs relied on these

material misrepresentations in deciding to purchase and consume Avandia to the Plaintiffs' detriment.

131. The damages sustained by Plaintiffs were a direct and foreseeable result of, and were proximately caused by GSK's misrepresentations, concealment and omissions.

132. GSK's conduct was willful, wanton, and reckless. Based on the intentionally dishonest nature of GSK's conduct, which was directed at the Plaintiffs and the public generally, GSK should also be held liable for punitive damages.

133. Any applicable statutes of limitation have been tolled by GSK's knowing and active concealment and denial of the facts alleged herein. The Plaintiffs and other members of the public who were prescribed and ingested Avandia for the treatment of diabetes have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part, and could not reasonably have discovered the fraudulent nature of GSK's conduct, and information and documents concerning the safety and efficacy of Avandia. Furthermore, due to the aforesaid allegations, Plaintiffs may rely on the discovery rule in pursuit of this claim.

134. By reason of the foregoing, Plaintiffs sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiffs seek punitive and exemplary damages against GSK in an amount to be determined upon the trial of this matter.

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT X
NEGLIGENT MISREPRESENTATIONS

135. Plaintiffs repeat and reiterate paragraphs 1-134 as if fully set forth herein.

136. GSK represented and marketed Avandia as being safe and effective.

137. After GSK became aware of the risks of ingesting Avandia, however, GSK failed to communicate to the Plaintiffs and other members of the general public, that the ingestion of this drug could have the increased risk of serious cardiovascular events.

138. Therefore, Plaintiffs bring this cause of action against GSK under the theory of negligent misrepresentation for the following reasons:

a) Plaintiffs incorporate all facts and allegations previously stated in this Complaint;

b) GSK failed to warn the Plaintiffs, and other consumers, of the defective condition of Avandia, as manufactured and/or supplied by GSK;

c) GSK, individually, and through its agents, representatives, distributors and/or employees, negligently misrepresented material facts about Avandia in that they made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, GSK made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations;

d) the above misrepresentations were made to the Plaintiffs, as well as the general public;

e) the Plaintiffs and the Plaintiffs' healthcare providers justifiably relied on GSK's misrepresentations; and

f) Consequently, the Plaintiffs' ingestion of Avandia was to the Plaintiffs' detriment. GSK's negligent misrepresentations proximately caused the Plaintiffs' injuries and monetary losses.

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT XI
NEGLIGENCE PER SE

139. Plaintiffs repeat and reiterate paragraphs 1-138 set forth herein.

140. GSK has an obligation not to violate the law.

141. GSK has violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301, *et seq.,* related amendments and codes and federal regulations promulgated thereunder, and other applicable state and federal laws, as alleged herein.

142. The Plaintiffs, as a purchasers and consumers of Avandia, are within the class of persons that statues described above are designed to protect.

143. Injury due to false, misleading and/or reckless advertising and promotion, and misbranding, misleading products and as otherwise set forth in this complaint, is the specific type of harm these statutes are designed to prevent.

144. GSK is responsible to Plaintiffs for injuries incurred for its violations of the statutes described above under the doctrine of negligence *per se*.

145. As a direct and proximate result of the negligence and negligence *per se* of GSK and each one individually and as a result of the GSK's actions and/or inactions as set forth in this complaint, the Plaintiffs were caused to suffer severe and permanent physical injuries as alleged herein.

WHEREFORE, Plaintiffs demand judgment against GSK, a sum which exceeds the jurisdictional limits of all lower courts which the jury would find to be fair, adequate and just, and in addition, Plaintiffs seek punitive and exemplary damages against Defendant in an amount to be determined upon the trial of this matter, together with costs and reasonable attorneys' fees.

COUNT XII
UNJUST ENRICHMENT

146. Plaintiffs repeat and reiterate paragraphs 1-145 as if fully set forth herein.

147. As an intended and expected result of its conscious wrongdoing, Defendant has profited and benefited from the purchases of Avandia by Plaintiffs.

148. Defendant has voluntarily accepted and retained these profits and benefits, derived from the Plaintiffs and others, with full knowledge and awareness that, as a result of Defendant's fraud and other conscious and intentional wrongdoing, Plaintiffs did not receive a product of the quality, nature or fitness that had been represented by Defendant or that Plaintiffs, as a reasonable consumers, expected.

149. By virtue of the conscious wrongdoing alleged in this Petition, Defendant have been unjustly enriched at the expense of the Plaintiffs, who are entitled to in equity, and hereby seek the disgorgement and restitution of Defendant's wrongful profits,

revenue and benefits, to the extent, and in the amount, deemed appropriate by the Court; and such other relief as this Court deems just and proper to remedy the Defendant's unjust enrichment.

WHEREFORE, Plaintiffs demand judgment against Defendant GSK, in the amount in excess $75,000.00, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action.

COUNT XIII
WRONGFUL DEATH

150. Plaintiffs repeat and reiterate paragraphs 1-149 as if fully set forth herein.

151. Where applicable, Plaintiffs are family members of Plaintiffs' decedents who have the right to bring the following Wrongful Death Action on behalf of the Plaintiffs' decedents' wrongful death beneficiaries.

152. Plaintiffs claim damages from Defendant for the pecuniary value of future services, support, society, comfort, and contribution of Plaintiffs' decedents that would have been rendered to the wrongful death beneficiaries for the expected remainder of Plaintiffs' decedents' life.

153. Plaintiffs further demand payment for Plaintiffs' decedents' funeral and burial expenses.

154. Plaintiffs also further demand payment for all economic losses suffered by the Plaintiffs decedents' survivors, including costs of administration and other expenses reasonably associated with the death of the Plaintiffs' decedents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against the Defendant as follows:

a. Awarding actual damages to the Plaintiffs incidental to the Plaintiffs' purchase and use of Avandia in an amount to be determined at trial;

b. Awarding punitive damages to the Plaintiffs;

c. Awarding pre-judgment and post-judgment interest to the Plaintiffs;

d. Awarding the costs and the expenses of this litigation to the Plaintiffs;

e. Awarding reasonable attorneys' fees and costs to the Plaintiffs as provided by law; and

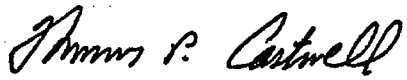
f. Granting all such other relief as Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all Counts and as to all issues.

Date: November 12, 2010.

Respectfully submitted,



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